IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CIPLA USA, INC.,	)	
	)	
Plaintiff/Counterclaim-Defendant,	)	
	)	
v.	)	Civil Action No. 22-552-GBW-SRF
	)	
IPSEN BIOPHARMACEUTICALS, INC.,	)	
	)	
Defendant/Counterclaim-Plaintiff.	)	
	)	
	)	

REPORT AND RECCOMENDATION

Presently before the court in this civil action for violations of the Lanham Act, 15 U.S.C. § 1125 (Section 43(a)), and related state law claims is Cipla USA, Inc.'s (hereinafter "Cipla") Motion to Dismiss (hereinafter "Motion") Ipsen Biopharmaceuticals, Inc.'s (hereinafter "Ipsen") counterclaims pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 88)[1] For the following reasons, I recommend that Cipla's Motion be **DENIED**.

I. BACKGROUND

On April 27, 2022, Cipla filed its complaint against Ipsen alleging violations of the Lanham Act and related state law causes of action. (D.I. 1) The parties are biopharmaceutical drug companies and each markets a drug injection product with lanreotide acetate as its active ingredient. (*Id.* at ¶¶ 1–2) Ipsen's product is called Somatuline® Depot. (*Id.* at ¶ 1) The product is a cancer treatment drug used to slow the growth of tumors. (*Id.*) Somatuline® Depot

[1] The briefing and related filings associated with this motion to dismiss are found at D.I. 1 (Cipla's Complaint), D.I. 87 (Ipsen's answer and countercomplaints), D.I. 89 (Cipla's opening brief in support of its motion to dismiss Ipsen's counterclaims), D.I. 97 (Ipsen's answering brief), D.I. 102 (Cipla's reply brief); and D.I. 147 (oral argument transcript).

entered the market in 2007 and for many years was the only lanreotide acetate injection approved by the Food and Drug Administration (hereinafter "FDA"). (*Id.*) On December 17, 2021, the FDA approved a lanreotide acetate injection product manufactured by InvaGen (hereinafter "InvaGen's Product"). (*Id.* at ¶ 2) InvaGen licenses its product for distribution by its affiliate, Cipla. (*See id.*) The FDA's approval was made under the Section 505(b)(2) pathway for New Drug Approvals (hereinafter "NDAs"), which establishes that a product is safe and effective for its intended use without rendering any findings of therapeutic equivalence. (*See id.* at ¶ 2; D.I. 87 at ¶¶ 22–23 (citing 21 U.S.C. § 355(b)(2)))

Cipla launched InvaGen's Product on February 10, 2022. (D.I. 1 at ¶ 43) This litigation arose shortly after Ipsen filed an application with the Center for Medicare and Medicaid Services (hereinafter "CMS") on February 24, 2022, seeking to have InvaGen's Product assigned the miscellaneous Healthcare Common Procedure Coding System (hereinafter "HCPCS") code, J3490, as opposed to the code assigned for Somatuline® Depot, J1930. (*Id.* at ¶ 46) Cipla alleges in the complaint that around the time the CMS application was filed, Ipsen began disseminating false or misleading statements to providers and wholesale distributors about impairment of their reimbursement claims for InvaGen's Product if submitted under an improper HCPCS code and accusations that Cipla wrongfully claimed InvaGen's Product was therapeutically equivalent to Somatuline® Depot. (*Id.* at ¶ 5) Cipla's complaint alleges that it experienced a drop in demand for InvaGen's Product after Ipsen made these false or misleading statements. (*Id.* at ¶ 51)

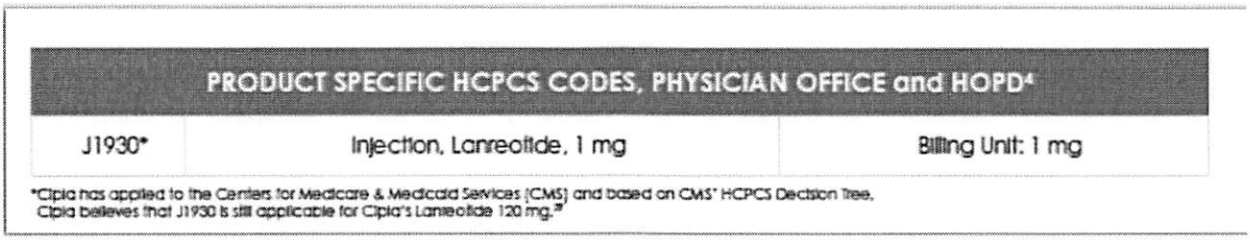
Ipsen moved to dismiss Cipla's complaint, arguing preclusion of judicial review under 42 U.S.C. § 1395w-3a(j)(1) and insufficiency of the pleadings under Rule 12(b)(6). (D.I. 16; D.I. 17) Following the referral of the motion, I issued a Report and Recommendation on March

1, 2023, recommending denial of the Motion. (D.I. 64) The Report and Recommendation was adopted by the District Judge on June 15, 2023. (D.I. 72) The background concerning CMS' regulatory authority and the assignment of HCPCS billing codes as well as the procedural history of earlier parallel litigation over Ipsen's challenges to certain FDA decisions regulating Somatuline® Depot are discussed in more detail in the court's Recommendation and the Memorandum Opinion adopting it. (D.I. 64; D.I. 72) In the interim, on July 6, 2022, CMS issued decisions creating a new HCPCS code for InvaGen's Product, J1932, and affirming the existing code for Somatuline® Depot. (D.I. 32 at 1) CMS' coding decision for InvaGen's Product became effective as of October 1, 2022. (*Id.*)

For purposes of the pending motion, the court will focus on the material relevant to Ipsen's counterclaim filed on June 29, 2023. (D.I. 87) Ipsen alleges that following the launch of InvaGen's Product, Cipla engaged in a campaign to deceive the market into thinking that InvaGen's Product was a generic version of and/or therapeutically equivalent to Somatuline® Depot and should be billed under the same HCPCS code. (*Id.* at ¶ 53)

Ipsen points to two examples of Cipla's conduct. First, it alleges that Cipla confused the marketplace through an earnings call with its CEO, Umang Vohra. (*Id.* at ¶¶ 54–56) In response to a question regarding the company's complex injectable portfolio, Vohra stated that "the timing" of InvaGen's Product launch was "meaningful" "*because we are the only generic player*." (D.I. 87 at ¶ 54 (emphasis in original); *see also* D.I. 90 Ex. B at 12) Vohra also stated that "Cipla ha[s] unlocked [a] major peptide asset in the US with [InvaGen's Product]" and that "[Cipla's] focus will be to continue to expand [Cipla's] peptide portfolio through internal development and partnerships strengthening [Cipla's] *high value complex generic pipeline*." (D.I. 87 at ¶ 55 (alterations and emphasis in original); *see also* D.I. 90 Ex. B at 5)

Second, Cipla distributed the following "Reference Guide to Reimbursement & Coding" that directed billers to utilize Somatuline® Depot's HCPCS code for InvaGen's Product, even though Cipla was allegedly aware that use of this code was inappropriate:



PRODUCT SPECIFIC HCPCS CODES, PHYSICIAN OFFICE and HOPD*		
J1930*	Injection, Lanreotide, 1 mg	Billing Unit: 1 mg

*Cipla has applied to the Centers for Medicare & Medicaid Services (CMS) and based on CMS' HCPCS Decision Tree, Cipla believes that J1930 is still applicable for Cipla's Lanreotide 120 mg.

(*Id.* at ¶¶ 57–58) Cipla purportedly would have known this because InvaGen's Product did not meet the criteria to be considered a multi-source drug[2] and would have customarily been billed to the miscellaneous HCPCS code. (*Id.* at ¶¶ 50–52) This harmed Ipsen because InvaGen's Product is priced lower Somatuline® Depot. (*Id.* at ¶ 63) As such, its reimbursement spread[3] was higher. (*Id.*) Because code J1930 reimbursed a flat dollar amount regardless of the drug prescribed, providers would receive more net reimbursement if they purchased InvaGen's Product and billed it to Somatuline® Depot's HCPCS code than if they purchased Somatuline® Depot itself. (*Id.*) This would incentivize providers to prescribe InvaGen's Product. (*Id.*) Ipsen's independent consultant, focalPoint™, estimates that roughly 80% of all reimbursement

[2] "[M]ulti-source" drugs are those that are rated as "therapeutically equivalent," "pharmaceutically equivalent and bioequivalent" to one another by the FDA. (D.I. 87 at ¶ 31 (citing 42 U.S.C. § 1395w-3a(c)(6)(C)(i))) Multi-source drugs all share the same HCPCS code and are reimbursed based off of a weighted average of the average sale's price from all products given that code. (*Id.* at ¶ 32) A single source drug is "not a multi-source drug" approved through an NDA. (*Id.* at ¶ 33 (quoting 42 U.S.C. § 1395w-3a(c)(6)(D))) A single source drug is "entitled" to its own HCPCS code, (*Id.* at ¶ 40), because a single source drug is reimbursed based solely off of its own pricing data. (*E.g. id.* at ¶ 34) CMS' decision to give InvaGen's Product its own HSPCS code did not take effect until October 1, 2022. (*Id.* at ¶ 51)

[3] "This delta between the cost for acquiring the cheapest product in a HCPCS code and the payment amount for the code is often referred to as a reimbursement spread." (D.I. 97 at 2 (internal quotations omitted))

claims submitted to Medicare Part B for InvaGen's Product have been through Somatuline® Depot's HCPCS code. (*Id.* at ¶ 65)

Cipla employees allegedly communicated to wholesalers and distributors directly that its drug was a generic version of Somatuline® Depot. (*Id.* at ¶ 68) It allegedly reinforced market confusion by not a adopting proprietary name for InvaGen's Product and marketing it as lanreotide acetate. (*Id.* at ¶ 61) This use of its "generic" name allegedly conveyed to the market that it was, in fact, a generic version of Somatuline® Depot. (*Id.*) Cipla was also allegedly complicit in allowing third parties, like pharmaceutical compendia (also called "price lists") — which aggregate information on drugs for physicians, wholesalers, distributors, and others — to assert that InvaGen's Product was a generic version of and/or therapeutically equivalent to Somatuline® Depot. (*Id.* at ¶ 67) Price lists customarily receive this information from the manufacturer. (*Id.*)

Ipsen alleges that Cipla's false and misleading statements caused widespread confusion in the marketplace. (*E.g. id.* at ¶ 69) At least two distributors allegedly sent email advertisements to their customers describing InvaGen's Product as "generic." (*Id.*) A large data platform allegedly listed InvaGen's Product alongside Somatuline® Depot's HCPCS code. (*Id.*) And one wholesaler allegedly linked Cipla's drug to Somatuline® Depot's ordering number, so customers could have received InvaGen's Product when they ordered Somatuline® Depot. (*Id.* at ¶ 71) This confusion persisted for over a year. (*Id.* at ¶ 70)

As a result of Cipla's false and misleading statements, Ipsen suffered financially due to a loss of sales for Somatuline® Depot, as well as reputational harm. (*Id.* at ¶¶ 82–83) Ipsen asserts claims for false advertising and unfair competition under the Lanham Act § 43(a), (*id.* at ¶¶ 87–89 ("Count I")), deceptive trade practices under the Delaware Uniform Deceptive Trade

Practices Act, (*id.* at ¶¶ 98–100 ("Count II")); *6 Del. C. § 2532*, and unfair competition, (*id.* at ¶¶ 104–07 ("Count III")), tortious interference with prospective economic advantage, (*id.* at ¶¶ 111–13 ("Count IV")), and trade libel. (*Id.* at ¶¶ 119–20 ("Count V"))

On July 20, 2023, Cipla filed this Motion to Dismiss Ipsen's counterclaim. (D.I. 88) The motion was referred to the undersigned judicial officer on July 21, 2023. Oral argument was held on October 19, 2023. (D.I. 106; D.I. 147)

II. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) permits a motion to dismiss a complaint, or in this instance, a countercomplaint, for failure to state a claim upon which relief can be granted. *See* Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the pleading and view them in the light most favorable to the counterclaim plaintiff. *See Umland v. Planco Fin. Servs.*, 542 F.3d 59, 64 (3d Cir. 2008).

To state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Although detailed factual allegations are not required, the complaint must set forth sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). A claim is facially plausible when the factual allegations allow the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *See Iqbal*, 556 U.S. at 663; *Twombly*, 550 U.S. at 555–56.

The court's determination is not whether the non-moving party "will ultimately prevail," but whether that party is "entitled to offer evidence to support the claims." *In re Burlington Coat*

Factory Sec. Litig., 114 F.3d 1410, 1420 (3d Cir. 1997) (internal citations and quotation marks omitted). This "does not impose a probability requirement at the pleading stage," but instead "simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of [the necessary element]." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Twombly*, 550 U.S. at 556). The court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679.

The court applies the Rule 8 pleading standard to the pending motion, as opposed to the heightened standard of Rule 9(b), because it is the same standard the court applied in deciding Ipsen's Motion to Dismiss.[4] (D.I. 72 at 9)

III. DISCUSSION

Cipla moves to dismiss Ipsen's counterclaim arguing it fails to plausibly plead a violation of the Lanham Act. (D.I. 89 at 11–17). Cipla also moves to dismiss Ipsen's related state law claims, contending that they arise from the same factual allegations of false or misleading statements as the Lanham Act claim. (*Id.* at 17–20) For the reasons which follow, factual disputes exist as to whether Cipla's statements were false or misleading, and I recommend that Cipla's motion be **DENIED**.

A. Lanham Act

Cipla alleges that Ipsen failed to properly plead a claim under Section 43(a) of the Lanham Act. In order to establish a Lanham Act violation, Ipsen must show:

[4] "[N]either the Supreme Court nor the Third Circuit has held that Rule 9(b) is the appropriate standard for Lanham Act claims." (D.I. 72 at 9 (citing *Peloton Interactive, Inc. v. ICON Heath & Fitness, Inc.*, C.A. No. 20-662-RGA, 2021 WL 2188219, at *5 (D. Del. May 28, 2021) (examining Lanham Act counterclaims under Rule 8 as opposed to a "heightened standard")))

1) that the defendant has made false or misleading statements as to his own product [] ;

2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience;

3) that the deception is material in that it is likely to influence purchasing decisions;

4) that the advertised goods traveled in interstate commerce; and

5) that there is a likelihood of injury to the plaintiff in terms of declining sales, loss of good will, etc.

(D.I. 72 at 7 (quoting *Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 91–92 (3d Cir. 2000)) Ipsen must plead this with "sufficiently detailed allegations regarding the nature of the alleged falsehood to allow [Cipla] to make a proper defense." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 632 F. Supp. 2d 362, 365 (D. Del. 2009) (internal citations and quotation marks omitted).

Cipla's Motion challenges Ipsen's allegations that Cipla made false and misleading statements that were disseminated to its customers. (D.I. 89 at § (I)(A)(1)) The court is directed to statements made by Cipla's CEO on an investor call and Cipla's "Reference Guide to Reimbursement & Coding." (*E.g. id.* at ¶¶ 53–60)

i. Cipla's Call with Investors

Cipla argues that the statements its CEO, Umang Vohra, made during the call with Cipla's investors on January 25, 2022 are cherry picked from the rest of the call and if viewed in context, are innocuous. (D.I. 89 at 12–13) It argues that the entire transcript of the call should be considered by the court because "Ipsen's claims quote and rely" on it.[5] (*Id.* at 8 n.9) In

[5] "In evaluating a motion to dismiss, [the court] may consider documents that are attached to or submitted with the complaint . . . and any matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, [and] items appearing in the record of the case." *Buck v. Hampton Twp. School Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (international quotations omitted). Additionally, Ipsen sent a letter to the court on October 13,

response, Ipsen argues that certain remarks on the call constituted false and misleading statements. Namely, Vohra referred to Cipla as the only "generic player" in the lanreotide acetate market and stated that Cipla would further seek to strengthen its "high value complex generic pipeline" allegedly in reference to InvaGen's Product. (D.I. 87 at ¶¶ 54–55)

The court cannot resolve disputed factual issues on a motion to dismiss. On its face, Cipla's motion raises a material issue of fact as to the context and interpretation of its representations to analysts and investors on the call. Notwithstanding consideration of the entire transcript, the court is effectively being asked to interpret the remarks made at different points in the transcript and then draw inferences adverse to the pleaded allegations. (D.I. 89 at 12–13)

Cipla cites *Sourovelis v. City of Philadelphia*, 246 F. Supp. 3d 1058, 1075 (E.D. Pa. 2017), arguing that Vohra's statements are "directly contradicted" by other statements made on the call, so this issue may be disposed of on a motion to dismiss. (*Id.* at 13) But under closer scrutiny, *Sourovelis* undermines Cipla's position. There, defendants argued that plaintiff could not plead claims that were at odds with the plain text of the regulation on which they depended. *Sourovelis*, 246 F. Supp. 3d at 1075. However, the court found that because the allegations did not directly contradict the regulation, they could proceed. *Id.* at 1075–76.

Here, the statements at issue during the earnings call do not unequivocally contradict Vohra's testimony. Rather, Cipla raises factual challenges in an effort to negate allegations that the statements were misleading as to whether InvaGen's Product was a generic drug. The same can be said with respect to Cipla's argument challenging whether Vohra's use of the term

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2023 stating that it has documentary evidence that support its counterclaims. (D.I. 131) But because the documents produced in discovery are not referenced in the pleading, they will not be considered in the court's recommendation.

"generic" was expressed as a term of art in the industry or as a more general and colloquial expression. (D.I. 89 at 13; D.I. 97 at 13)

Furthermore, Ipsen has sufficiently pled marketplace confusion. It alleges that the contents of the call were disseminated to customers, wholesalers, and distributors as part of a coordinated deception campaign. (D.I. 87 at ¶¶ 53, 56) Ipsen's consultant, focalPoint™, has estimated that 80% of all Medicare Part B claims for InvaGen's Product have used Somatuline® Depot's HCPCS code. (*Id.* at ¶ 65) Major pharmaceutical distributors allegedly created advertisements stating that InvaGen's Product was a generic version of Somatuline® Depot, and this confusion persisted for nearly a year after InvaGen's Product came to market. (*Id.* at ¶¶ 69–70) Some distributors potentially sent InvaGen's Product to customers who ordered Somatuline® Depot. (*Id.* at ¶¶ 71–72) And although Cipla is correct that it has no responsibility to police third parties' false statements about its products, (*e.g.* D.I. 89 at 3), Ipsen has plausibly alleged marketplace confusion. (D.I. 97 at 14 n.8)

Even if it is determined that Cipla's alleged misrepresentations on the earnings call have been plausibly pled, Cipla maintains that dismissal is warranted because such statements do not satisfy the commercial advertising or promotion requirements of the Lanham Act. (D.I. 89 at 14–15) Cipla contends the statements were made to inform and influence shareholders — rather than customers — and there was no evidence that the statements made on the call were ever disseminated to the public. (*Id.*) For the following reasons, the court recommends that the court find that Ipsen has plausibly pled that Cipla's statements qualify as commercial advertising or promotion under the Lanham Act.

Although no binding Third Circuit precedent exists, this court has consistently utilized the *Gordon & Breach* test to determine whether a representation qualifies as a commercial

advertisement or promotion. *Gordon & Breach Sci. Publishers v. Am. Inst. of Physics*, 859 F. Supp. 1521, 1535–36 (S.D.N.Y. 1994); *e.g. Incarcerated Ent., LLC v. CNBC, LLC*, 331 F. Supp. 3d 352, 358–59 (D. Del. 2018); *Accenture Glob. Servs. GMBH v. Guidewire Software Inc.*, 581 F. Supp. 2d 654, 666–67 (D. Del. 2008). Under *Gordon & Breach*, commercial advertisement or promotion requires the following elements: "(1) commercial speech; (2) by a defendant in commercial competition with the plaintiff; (3) for the purpose of influencing consumers to buy the defendants [sic] goods or services . . . (4) [] disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry." *Incarcerated Ent.*, 859 F. Supp. 3d at 358 (quoting *Gordon & Breach*, 859 F. Supp. at 1535–36) (alterations in original). Cipla's arguments focus solely on the fourth requirement, whether the comments made on the investor call were disseminated to customers. (D.I. 89 at 14–15; D.I. 102 at § (I)(A)(2))[6]

In *Registered Agent Solutions. v. Corporation Service Co.*, 2022 WL 911253, at *3 (D. Del. March 28, 2022), the court held that to survive a motion to dismiss, the pleading must allege "enough facts to raise a reasonable expectation that discovery will reveal evidence of [dissemination]." *Id.* at *3 (quoting *N.J. Physicians United Reciprocal Exch. v. Boynton & Boynton, Inc.*, 2014 WL 317179, at *5 (D.N.J Jan. 28, 2014)). To do that, it must "identify some medium or means through which [defendant] disseminated information to a particular class of consumers" *Id.* (quoting *Podiatrist Ass'n, Inc. v. La Cruz Azul*, 332 F.3d 6 (1st Cir. 2003)).[7]

[6] Cipla acknowledged at oral argument that it is not advancing this argument with respect to Ipsen's allegations concerning Cipla's Reference Guide to Reimbursement & Coding, as there is no dispute that the guide was disseminated to customers, among others. (D.I. 147 at 13:19–14:4)

[7] The court ultimately found that an allegation of a single phone call to a single customer on an unspecified date was not enough to plausibly plead dissemination. *Registered Agent Sols.*, 2022 WL 911253, at *3.

Cipla directs the court to two out of district cases supporting its argument that the earnings call was not properly disseminated to its customers. (D.I. 147 at 11 ¶¶ 5–25, 12 ¶¶ 1–7) In *Genus Lifesciences Inc. v. Lannett Co.*, 378 F. Supp. 3d 823 (N.D. Cal. 2019), the court found that statements made by the defendant during a call with investors could not state a Lanham Act claim because there were no allegations that the call reached its customers. *Id.* at 835–36. The second case on which Cipla relies is *In re Syngenta AG MIR 162 Corn Litig.*, 131 F. Supp. 3d 1177 (D. Kan. 2015). The court held that a call with investors posted to the internet that conveyed a false or misleading statement did not create a cause of action under the Lanham Act because there were no facts pled that the earnings call was accessed by defendant's customers. *Id.* at 1225–26.

The court is not persuaded by Cipla's argument that statements made on investor calls can never give rise to a Lanham Act claim. *Id.* at 1226 (noting that the defendant's cited cases "did not rule that statements in such conference calls could never support a Lanham Act claim; rather, in each case, the court concluded that the plaintiff had not alleged sufficient facts to satisfy the requirements that the statements be made for the purpose of influencing customers and be sufficiently disseminated.") The cases are further distinguishable because Ipsen has pled that Cipla's earnings call was part of an overarching campaign to deceive its customers and that the call's contents, upon information and belief, reached its customers. (*E.g.* D.I. 87 at ¶ 56 ("[T]hese statements [by Vohra] were meant to convey to the marketplace — including distributors, price lists, insurers, and *customers* — that the Cipla LA Product was a generic product.") (emphasis added)) In addition, Ipsen alleges at paragraph 69 that multiple distributors and a data platform began listing InvaGen's Product as a generic drug after the January, 2022 earnings call. (*Id.* at ¶ 69 ("For example, in January 2022, a distributor (Distributor A) sent an

email to its customers announcing that Cipla's LA Product was a 'generic lanreotide' that was available. Another major distributor (Distributor B) sent a similar announcement to its customers in March 2022, advertising the availability of the Cipla LA Product, which it described as a generic lanreotide. Indeed, Distributor B's ordering website and documents expressly presented Cipla's LA Product as a generic version of Somatuline Depot.") Ipsen's pleadings plausibly allege "enough facts to raise a reasonable expectation that discovery will reveal evidence" of dissemination. *Boynton & Boynton, Inc.*, 2014 WL 317179, at *5 (citing *Bell Atl. Corp. v. Twombly,* 550 U.S. 544, 547 (2007)). This inquiry "ordinarily" creates a "question of fact inappropriate for resolution on a motion to dismiss." *Wakefern Food Corp. v. Marchese*, 2021 WL 3783259, at *4 (D.N.J. Aug. 26, 2021).

Ipsen argues in its answering brief that a recording of the call and its transcript were disseminated to customers because they were all posted to Cipla's website. (D.I. 97 at 7, 7 n.5) These facts will not be considered because they were not expressly raised in Ipsen's counterclaim, but the court need not rely on them to buttress its recommendation that dissemination has been plausibly pled by Ipsen. *Pennsylvania ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (quoting *Car Carriers, Inc. v. Ford Motor Co.,* 745 F.2d 1101, 1107 (7th Cir. 1984) ("[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss."); *Burns v. Stratos*, 2023 WL 4014474, at *3 (3d Cir. June 15, 2023) ("[A] party may not amend its complaint through its brief."). *Sigma Dynamics, Inc. v. E.Piphany, Inc.*, 2004 WL 2533220 (N.D. Cal Nov 8, 2020), weighs solely on this point and is thus inapposite. (D.I. 147 at 12 ¶¶ 8–24)

Therefore, whether the statements on the earnings call constitute commercial advertising or promotion and were disseminated to Cipla's customers should be left to the factfinder. I

recommend that court **DENY** Cipla's motion to dismiss the alleged Lanham Act counterclaim arising from statements made on the earnings call.

ii. Cipla's Lanreotide Acetate Product Billing "Reference Guide"

Cipla moves to dismiss Ipsen's counterclaim that the "Reference Guide to Reimbursement & Coding" Cipla distributed to its customers "improperly directed recipients to use the HCPCS code that is applicable to Somatuline Depot — J1930 — for Cipla's LA Product." (D.I. 87 at ¶ 57; *see also* D.I. 89 at 16–17) Cipla argues that its opinion on HCPCS coding is not actionable under the Lanham Act. (*Id.*) In response, Ipsen argues that Cipla couched a false statement of fact in the language of an opinion to avoid liability. (D.I. 97 at 18) Cipla was aware or should have been aware that its product did not fall under Somatuline® Depot's HCPCS code because there is no factual foundation for Cipla to reasonably believe that its product belongs in the same HCPCS code, and it would not have applied to CMS for a new code if that were the case. (*See id.* at 18–19; *e.g.* D.I. 87 at ¶ 77) For the following reasons, I recommend denying Cipla's motion to dismiss.

"Only statements of fact capable of being proven false are actionable under the Lanham Act," not statements solely of opinion, because the target audience "is likely to assume only that the communicator believes the statement, not that the statement is true." *Parker v. Learn Skills Corp.*, 530 F. Supp. 2d 661, 679 (D. Del. 2008). However, statements of opinion that convey a false factual basis on which an advertiser came to its opinion may still be actionable. *Cf Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 196 (2015)

(holding that courts must ask if a party "lacked the basis" for making a statement of opinion);[8] *see also Liqwd, Inc. v. L'Oréal USA, Inc.*, 2019 WL 10252725, at *7 (D. Del. Apr. 30, 2019).

Ipsen directs the court to several allegations in its counterclaim it contends plausibly allege false and misleading statements by Cipla. Cipla listed the HCPCS code on its reference guide as J1930, the same as Ipsen's Somatuline® Depot. (*See* D.I. 87 at ¶ 58) Cipla sent this to its customers, leading to confusion in the marketplace. (*Id.* at ¶¶ 59, 62) It was allegedly aware that only multi-source drugs share HCPCS codes and that InvaGen's Product met the definition of a single source drug. (*Id.* at ¶¶ 50, 77) And Cipla was aware that multi-source drugs must be therapeutically equivalent to one another and that InvaGen's Product was not therapeutically equivalent to Somatuline® Depot. (*E.g. id.* at ¶¶ 31, 49) Thus, grouping its product under Somatuline® Depot's HCPCS code was meant to signal to the market that the two are therapeutically equivalent. This was furthered by Cipla's use of the drug's generic name, lanreotide acetate. (*Id.* at ¶ 61)

Cipla asserts that its reference guide only conveys a statement of opinion, as evidenced by the footnote underneath the guide that noted Cipla "*believes* that J1930 is [] applicable for Cipla's Lanreotide" product. (D.I. 89 at 16 (quoting D.I. 87 at ¶ 58) (emphasis in original)) Cipla claims the footnote in the reference guide rested on the factual assumption that its decision to list InvaGen's Product under the J1930 code was a result of its interpretation of the HCPCS

[8] *Omnicare* considered claims under the Securities Act, rather than claims under the Lanham Act. It was noted in the opinion that its "principles are not unique to § 11 [of the Securities Act]: They inhere, too, in much common law respecting the tort of misrepresentation," and circuit courts have applied the reasoning to a variety of factual situations. 575 U.S. at 191; *see generally ThermoLife Intern., LLC v. Gaspari Nutrition Inc.*, 648 F. App'x 609, 614–15 (9th Cir. 2016) (Lanham Act); *United States v. AseraCare, Inc.*, 938 F.3d 1278, 1302 (11th Cir. 2019) (False Claims Act); *Loreley Fin'ing No. 3 Ltd. v. Wells Fargo Secs., LLC*, 797 F.3d 160, 189 n.21 (2d Cir. 2015) (common law fraud).

Decision Tree. (D.I. 87 at ¶ 58; D.I. 97 at 18–19 (citing *Omnicare*, 575 U.S. 175 (2015))) Ipsen challenges this factual assertion by stating that it was only meant to insulate Cipla from liability for misleading consumers. (*Id.* at 18–19)

As noted in the Report and Recommendation on Ipsen's Motion to Dismiss, statements susceptible to proof by way of objectively verifiable facts are actionable under the Lanham Act. (D.I. 64 at 12 (citing *Shure Inc. v. Clearone, Inc.*, C.A. No. 19-1343-RGA-CJB, 2020 WL 2839294, at *7 (D. Del. June 1, 2020))) Cipla' argument raises questions of fact that cannot be resolved on a motion to dismiss. On the one hand, Cipla argues that it never said its product was therapeutically equivalent to Somatuline® Depot, and there is no dispute about the lack of therapeutic equivalence. But at oral argument, it contended that "because the products were so close, because there was not a meaningful therapeutic distinction between them in the same active ingredient, the same method of administration, and overlapping indications, we thought the existing [HCPCS] code covered the product." (D.I. 147 at 41:24–42:6) Whether such positions can be reconciled is a question for the factfinder, and at this stage, the court recommends that Ipsen's allegations are plausible.

Cipla's argument that the footnote underneath the graphic directly contradicts Ipsen's allegations raises a question of fact which cannot be addressed on a motion to dismiss. (*E.g.* D.I. 89 at 16–17) Relatedly, Cipla directs the court to consider the remainder of its reference guide, which arguably further confirms that Cipla correctly represented that it was seeking coding guidance from CMS. (D.I. 102 at 9) The court cannot interpret the meaning and context of the statements in Cipla's reference guide in resolving a motion to dismiss where allegations in the pleadings must be viewed in the light most favorable to Ipsen.

Therefore, I recommend that the court **DENY** Cipla's motion to dismiss Ipsen's Lanham Act claims arising from Cipla's Reference Guide to Reimbursement & Coding.

B. State Law Claims (Counts II–V)

In addition to the Lanham Act violations, Cipla moves to dismiss Ipsen's Delaware state law and common law tort claims. (D.I. 89 at 17) Cipla argues that the claims should be dismissed because they all rely on the same allegations of false and misleading statements underlying the Lanham Act claims. (*Id.*) Ipsen argues that two of the state law claims — unfair competition and tortious interference — do not require a false statement, and because the Delaware Uniform Deceptive Trade Practices Act (hereinafter "DTPA") has a lower pleading threshold than the Lanham Act, the state claims can survive dismissal even if the Lanham Act claims are dismissed. (D.I. 147 at 35:17–36:21) Because the Lanham Act claims have been plausibly pled and Cipla has not advanced arguments as to why each of these state law counts are deficient, the court recommends the motion to dismiss the state law claims be **DENIED**.

IV. CONCLUSION

For the foregoing reasons, I recommend the court **DENY** Cipla's Motion to Dismiss. (D.I. 88)

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(l)(B), Fed. R. Civ. P. 72(b)(l), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

The parties are directed to the court's Standing Order For Objections Filed Under Fed, R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, http://www.ded.uscourts.gov.

Dated: January 26, 2024

Sherry R. Fallon
United States Magistrate Judge